

CLINICAL DEVELOPMENT PROGRAM

The safety and efficacy of the agents for uses under investigation have not been established. Pipeline molecules may not receive regulatory approval and become commercially available for the uses being investigated. The information provided about new molecules being studied is for scientific information exchange purposes only with no commercial intent. For more information on our pipeline, please visit lillyoncologypipeline.com.

This document was commissioned by Lilly Medical and is intended to be used by HCPs for medical, scientific, and educational purposes.

Pipeline information is current through August 2026.

LILLY IS COMMITTED TO REDUCING BARRIERS AND MAKING LIFE BETTER FOR PEOPLE LIVING WITH CANCER.

Lilly is committed to the development of patient-tailored therapeutics that integrate disease and target biology with drug characteristics in order to optimize treatments for patients. Our multidisciplinary approach allows for the translation of molecular and cellular discoveries into clinically meaningful outcomes. Key to this approach is Lilly's extensive and growing catalog of biomarkers.

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CLINICAL DEVELOPMENT PIPELINE

BREAST CANCER

3	Abemaciclib CDK4/6 Inhibitor EBC: HR+/HER2-	NCT03155997 (monarchE)	
3	Imlunestrant Selective ER Degradar EBC: ER+/HER2-	NCT05514054 (EMBER-4)	
3	Imlunestrant Selective ER Degradar MBC: ER+/HER2-	NCT04975308 (EMBER-3)	
2	Imlunestrant Selective ER Degradar EBC: ER+/HER2-	NCT07287098 (preEMBER)	RECRUITING
3	Tersolisib Pan-Mutant Selective PI3Kα Inhibitor MBC: HR+/HER2-, PIK3CAm	NCT07174336 (PIKALO-2)	RECRUITING
1/2	Tersolisib Pan-Mutant Selective PI3Kα Inhibitor MBC: HR+/HER2-, PIK3CAm	NCT05768139 (PIKALO-1)	RECRUITING
1	LY4257496 GRPR Radioligand MBC: ER+/HER2-, ER+/HER2+	NCT07114601 (OMNIRAY)	RECRUITING
1	LY4337713 FAP Radioligand MBC: HR+/HER2-, HR+/HER2+, HR-/HER2+, TNBC	NCT07213791 (FIREBOLT)	RECRUITING

PROGRAM KEY

- Small Molecule
- ADC
- Radioligand Therapy
- T-Cell Engager/
Engineered Biologic

ADC=Antibody-Drug Conjugate; CDK=Cyclin-Dependent Kinase; EBC=Early Breast Cancer; ER=Estrogen Receptor; FAP=Fibroblast Activation Protein; GRPR=Gastrin-Releasing Peptide Receptor; HER2=Human Epidermal Growth Factor Receptor 2; HR=Hormone Receptor; MBC=Metastatic Breast Cancer; PI3Kα=Phosphoinositide 3-Kinase Alpha; PIK3CAm=Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha Mutation; TNBC=Triple-Negative Breast Cancer.

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CLINICAL DEVELOPMENT PIPELINE

LUNG CANCER

3	Selpercatinib RET Inhibitor NSCLC	NCT04819100 (LIBRETTO-432)	
3	Olomorasib KRAS G12C Inhibitor Stage II-III NSCLC	NCT06890598 (SUNRAY-02)	RECRUITING
3	Olomorasib KRAS G12C Inhibitor Metastatic NSCLC	NCT06119581 (SUNRAY-01)	RECRUITING
1/2	Olomorasib KRAS G12C Inhibitor NSCLC	NCT04956640	
1	LY4050784 SMARCA2 (BRM) Inhibitor NSCLC	NCT06561685	RECRUITING
1	LY4175408 PTK7 ADC NSCLC, SCLC	NCT07046923	RECRUITING

SUPPORTIVE CARE

2	LY3537021 Incretin (LAGIPRA) Chemotherapy-Induced Nausea & Vomiting, Select Solid Tumors	NCT07169851	RECRUITING
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PROGRAM KEY

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- T-Cell Engager/
Engineered Biologic

ADC=Antibody-Drug Conjugate; BRM=Brahma Homolog; KRAS=Kirsten Rat Sarcoma Virus; NSCLC=Non-Small Cell Lung Cancer; PTK7=Protein Tyrosine Kinase-7; RET=Rearranged During Transfection; SCLC=Small Cell Lung Cancer; SMARCA2=Switch/Sucrose Non-Fermentable (SWI/SNF)-Related, Matrix-Associated, Actin-Dependent Regulator of Chromatin Subfamily A Member 2.

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CLINICAL DEVELOPMENT PIPELINE

GYNECOLOGIC CANCER

3	Sofetabart mipitecan FRα ADC PROC, PSOC	NCT07213804 (FRAmework-01)	RECRUITING
1	Sofetabart mipitecan FRα ADC Low Grade Serous Ovarian, Endometrial, Cervical	NCT06400472	RECRUITING
1	LY4257496 GRPR Radioligand Endometrial Cancer	NCT07114601 (OMNIRAY)	RECRUITING
1	LY4337713 FAP Radioligand Ovarian Cancer	NCT07213791 (FiREBOLT)	RECRUITING
PC	LY4336619 ALPPL2 x CD3 Bispecific T-Cell Engager/Engineered Biologic Ovarian, Endometrial		

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- T-Cell Engager/
Engineered Biologic

ADC=Antibody-Drug Conjugate; ALPPL2=Alkaline Phosphatase Placental-Like 2; CD3=Cluster of Differentiation 3; FAP=Fibroblast Activation Protein; FRα=Folate Receptor Alpha; GRPR=Gastrin-Releasing Peptide Receptor; LAGIPRA=Long-Acting Glucose-Dependent Insulinotropic Polypeptide Receptor Agonist; PROC=Platinum-Resistant Ovarian Cancer; PSOC=Platinum-Sensitive Ovarian Cancer.

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CLINICAL DEVELOPMENT PIPELINE

GENITOURINARY CANCER

3	Vepugratinib FGFR3 Inhibitor Urothelial Cancer	NCT07218380 (FORAGER-2)	RECRUITING
1	Vepugratinib FGFR3 Inhibitor Urothelial Cancer	NCT05614739 (FORAGER-1)	RECRUITING
1	LY4052031 Nectin-4 ADC Urothelial Cancer	NCT06465069 (NEXUS-01)	RECRUITING
1	LY4257496 GRPR Radioligand Prostate Cancer	NCT07114601 (OMNIRAY)	RECRUITING

GASTROINTESTINAL CANCER

1/2	Olomorasib KRAS G12C Inhibitor PDAC, CRC	NCT04956640	
1	LY3962673 KRAS G12D Inhibitor PDAC, CRC	NCT06586515 (MOONRAY-01)	RECRUITING
1	LY4257496 GRPR Radioligand CRC	NCT07114601 (OMNIRAY)	RECRUITING
1	LY4337713 FAP Radioligand PDAC, CRC, Gastric, Esophageal, CCC	NCT07213791 (FiREBOLT)	RECRUITING

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Engineered Biologic

ADC=Antibody-Drug Conjugate; CCC=Cholangiocarcinoma; CRC=Colorectal Cancer; FAP=Fibroblast Activation Protein; FGFR3=Fibroblast Growth Factor Receptor 3; GRPR=Gastrin-Releasing Peptide Receptor; KRAS=Kirsten Rat Sarcoma Virus; PDAC=Pancreatic Ductal Adenocarcinoma.

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CLINICAL DEVELOPMENT PIPELINE

MULTIPLE SOLID TUMOR TYPES

2	Abemaciclib CDK4/6 Inhibitor Pediatric and Young Adults With High-Grade Glioma	NCT06413706	
1/2	Tersolisib Pan-Mutant Selective PI3Kα Inhibitor Select Solid Tumors	NCT05768139 (PIKALO-1)	RECRUITING
1	LY4050784 SMARCA2 (BRM) Inhibitor Select Solid Tumors	NCT06561685	RECRUITING
1	LY3962673 KRAS G12D Inhibitor Select Solid Tumors	NCT06586515 (MOONRAY-01)	RECRUITING
1	Vepugratinib FGFR3 Inhibitor Select Solid Tumors	NCT05614739 (FORAGER-1)	RECRUITING
1	LY4337713 FAP Radioligand Select Solid Tumors	NCT07213791 (FIREBOLT)	RECRUITING
1	LY4257496 GRPR Radioligand Select Solid Tumors	NCT07114601 (OMNIRAY)	RECRUITING
1	LY4175408 PTK7 ADC Select Solid Tumors	NCT07046923	RECRUITING
1	Sofetabart mipitecan FRα ADC Select Solid Tumors	NCT06400472	RECRUITING

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CLINICAL DEVELOPMENT PIPELINE

MULTIPLE SOLID TUMOR TYPES (CONTINUED)

PC	LY5775377 TROP2 Dual-Payload (Topoli/ATRI) ADC Select Solid Tumors
PC	LY4336619 ALPPL2 x CD3 Bispecific T-Cell Engager/Engineered Biologic Select Solid Tumors

HEMATOLOGY

3	Pirtobrutinib Non-Covalent BTK Inhibitor CLL/SLL	NCT05254743 (BRUIN CLL-314)	RECRUITING PART 2
3	Pirtobrutinib Non-Covalent BTK Inhibitor CLL/SLL	NCT05023980 (BRUIN CLL-313)	
3	Pirtobrutinib Non-Covalent BTK Inhibitor CLL/SLL	NCT04965493 (BRUIN CLL-322)	
3	Pirtobrutinib Non-Covalent BTK Inhibitor MCL	NCT04662255 (BRUIN MCL-321)	
2	Pirtobrutinib Non-Covalent BTK Inhibitor CLL/SLL	NCT06588478 (BRUIN CLL-211)	RECRUITING
1/2	Pirtobrutinib Non-Covalent BTK Inhibitor ITP	NCT06721013	RECRUITING
1	LY4584180 BCL6 Molecular Glue B-Cell Malignancies	NCT07226843 (NOVA-BCL6-1)	RECRUITING

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HEMATOLOGY (CONTINUED)

1	LY5830966 Type II JAK2 Inhibitor Myeloproliferative Neoplasms	NCT06343805 (AJX-101)	RECRUITING
1	LY4152199 BAFF-R x CD3 Bispecific T-Cell Engager B-Cell Malignancies	NCT07101328 (BAF_Frontier-1)	RECRUITING
1	LY5858489 In Vivo CAR-T Multiple Myeloma	NCT07075185 (KLN-001; inMMMyCAR)	RECRUITING

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To learn more about Lilly's commitment
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[LillyOncologyPipeline.com](https://lillyoncologypipeline.com).

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